WR 12/4/02
RJA 12/5/02

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES
REGULATION OF NEW CHEMICAL SUBSTANCES
PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice
	)	Number:
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[ ]	)	P89-0538
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REVOCATION OF CONSENT ORDER

PREAMBLE

Pursuant to section 5(a) (1) (A) of the Toxic Substances Control Act ("TSCA") and 40 CFR Part 720, [ ] submitted to the Environmental Protection Agency ("EPA" or "the Agency") on March 27, 1989, premanufacture notice ("PMN") P89-538 for [ ]. The PMN described the intended use of the substance as [ ]. [ ] is the successor in interest to [ ], for all technology and manufacturing rights associated with the PMN substance, P89-538. [ ] is a division of [ ]. In 1997, [ ] merged with [ ]. [ ] ("the Company") is the successor in interest for all the technology and assets of [ ] including [ ], its [ ], and thereby P89-538.

In its initial review of the PMN substance, EPA determined that this PMN substance will be produced in substantial quantities, there may be significant or substantial human exposure to the substance, and the PMN substance may reasonably be anticipated to enter the environment in substantial quantities under uncontrolled conditions of manufacture, import, processing, distribution in commerce, use and disposal. Therefore, pursuant to section 5(e) of TSCA, EPA and the Company entered into a Consent Order, effective October 23, 1992, which placed certain restrictions on manufacturing, processing, use, and distribution in commerce of the PMN substance.

Under the terms of the Consent Order, the Company submitted the following studies on P-89-538: pharmacokinetics; mutagenicity; 90-day repeated dose; oral developmental toxicity in two species; two-generation reproductive toxicity; water solubility; hydrolysis; ready

biodegradation; and biodegradation in soil studies. EPA has completed its review of the studies and determined that each study is scientifically valid. Agency review found that the PMN substance is rapidly absorbed and metabolized by the body and the substance is not mutagenic. Testing on systemic toxicity demonstrated no NOAEL in females and a NOAEL of 200 ppm in males, while the neurotoxicity battery resulted in a NOAEL of 1000 ppm for males and females. The results of the oral developmental toxicity study in rats were: a fetotoxicity NOAEL of 500 mg/kg/day and a maternal toxicity LOAEL of 500 mg/kg/day. In rabbits, the fetotoxicity NOAEL was 200 mg/kg/day (highest dose tested), while the maternal toxicity NOAEL was 50 mg/kg/day. At the highest dose level (3200 ppm) in the two-generation reproduction study, the animals had consistently lower weight gains compared with controls before and during gestation. At the highest dose, the absolute weights of the kidneys in males and the adrenals and spleen in females were lower than controls, presumably reflecting the body weight changes. Epididymis changes occurred in all the animals at 3200 ppm, with the effect less pronounced at 800 ppm and not evident at 200 ppm. Hydrolysis and biodegradation data indicated the half-life of the PMN substance was a few days. In addition, the Company submitted a revised Material Safety Data Sheet and product label.

In a letter dated July 6, 1998, the Company petitioned to have the Tier III testing requirements waived for the PMN substance. Based on the results of the studies and the diminished exposure of the chemical through use of protective gloves, the Agency determined that the PMN substance poses a low risk of injury to human health and the environment and that

the two generation and bioassay studies were no longer needed.

In a letter dated November 8, 1999, the Company requested that the Agency revoke the Consent Order and the corresponding SNUR. Because the Agency is unable to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the PMN substances may present an unreasonable risk of injury to human health and the environment, EPA is now revoking the Consent Order. Although the Agency is revoking the Consent Order, the Agency will modify the existing Significant New Use Rule ("SNUR") to require adequate dermal protection to reduce worker exposure to P-89-538.

REVOCATION OF CONSENT ORDER

Under the authority of section 5(e) of the Toxic Substances Control Act (15 U.S.C. 2604(e)) and Section IV of the Consent Order by and between the Environmental Protection Agency (EPA) and [ ] (the Company), effective October 23, 1992, EPA, upon request of the Company, hereby revokes in its entirety the Consent Order for the Premanufacture Notice P89-0538. This revocation is effective on the date of signature.

11/26/02
Date

(S)
Wardner G. Penberthy, Acting Director
Chemical Control Division (7405M)
Office of Pollution Prevention and Toxics